DETAILED ACTION

This final action is in response to the amendment received on 3/13/08

Claim Objections

1. Claims 1, 4, and 14 are objected to because of the following informalities:

In line 8 claim 1, the unit “mg/l” should be replaced with “mg/L”. In line 13 of claim 14, Applicant added a temperature range for the heated nitrogen without including the Fahrenheit unit as described on page 1, numbered line 23 of the disclosure. For claim 4, Applicant has added the limitation "heated insert gas". The wording of this phrase is unclear. It should be --heated inert gas--.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

For claim 1: In line 8, Applicant added the sterilant concentration range of "150 to 550 mg/L" whereas the specification on page 4 numbered line 19, teaches a range of "400 to 550 mg/L".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 3-4, 6, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joslyn (U.S.P.N. 4,770,851) in view of Popescu et al (U.S.P.N. 5,464,580) and further in view of Irons et al (U.S.P.N. 3,494,725).

Regarding claim 1, Joslyn discloses a method for sterilizing industrial products

(col.1, lines 12-14) including, in combination, the steps of conditioning industrial products to be sterilized by placing the products in a single chamber (figure 1:16), first evacuating the single chamber (col.3, lines 37-39) to a certain vacuum pressure, adding steam (col.3, lines 44-45) and heated air (col.3, lines 57-60) into the single chamber to increase the pressure within the chamber by a certain amount and re-evacuating the single chamber (col.4, lines 1-3) by pulling the heated air from the chamber by a certain vacuum pressure amount to or near the value of the first evacuating pressure (figure 2: points 102 and 106 where both values represent P1), and sterilizing the products by injecting a sterilant gas into the single chamber (col.4, lines 31-32) to raise the chamber pressure by a certain amount (figure 2:111 and col.4, lines 33-36) with ethylene oxide gas having a concentration value of 650 mg/L (see Table 2). As to the claimed concentration range value for ethylene oxide, Joslyn illustrates this value as an example and does not require the concentration to be at this value. It is noted in the specification on page 4, second paragraph that Applicant teaches higher and lower values of ethylene oxide may be used and that the concentration amount depends on the type of the product being sterilized. It would have been obvious to one of ordinary skill in the art at the time of the invention to reduce the ethylene oxide concentration from 650 mg/L to 550 mg/L as such is considered well within the purview of the artisan to determine the proper concentration as an obvious routine of experimentation. Only the expected results would be attained.

Furthermore, Joslyn teaches the following: using the ethylene oxide gas as the overpressure gas at a certain pressure value instead of using an inert gas as required

by the claim (col.4, lines 63-65), holding the product in the single chamber for a dwell time (see the two hours ethylene oxide sterilization described in Table 2) determined for product being sterilized until the products is sterilized, degassing the product by a gas wash that includes steam (col.5, lines 9-10) by evacuating the chamber to a certain pressure value (considered P1 in figure 3 and as described in col.5, lines 15-18) where steam is used to evacuate the chamber (col.5, lines 49-50) and re-pressurizing with heated air or steam to a certain pressure value (col.5, lines 29-32) with necessary repetitions of evacuating and re-pressuring the chamber to degas the products (col.6, lines 25-32), wherein heated air (col.3, lines 57-59) facilitates the steam to enter into cervices of the product, ethylene oxide gas compresses the steam so that both enters into cervices of the product (col.4, lines 36-41), the combined steam and sterilant gas together are removed from the product by the repetitions of evacuating and re-pressurizing the chamber with heated air (col.5, lines 29-30), releasing the degassed products after the steps of conditioning the products, sterilizing the products, and de-gassing the products are completed (col.6, lines 32-34) to validated process parameters (col.6, lines 37-45 and Table 2) which render to the products specific product and process evidence of appropriate level of lethality and residual reduction. Joslyn fails to teach the following: evacuating to a pressure of from 1 to 4 inches of mercury, adding pulsing steam and heated inert gas into the single chamber to increase chamber pressure by at least 2 inches of mercury, re-evacuating by pulling the inert gas from the chamber by 2 inches of mercury, injecting the sterilant into the single chamber to raise the chamber pressure by at least 9 inches of mercury, introducing an overpressure of

inert gas into the single chamber in the range of from 5 to 15 inches of mercury, degassing the products to a pressure of less than 3 inches of mercury, re-pressurizing with inert gas to a pressure of from less than 3 to up to 55 inches of mercury, the inert gas facilitates the steam and sterilant gas entering into cervices of the product, and the steam and the sterilant gas combine without condensing.

Popescu discloses a method for sterilizing industrial products with ethylene oxide gas (col.1, lines 6-11) that includes the following: evacuating to a pressure of from 1.77 inches of mercury (col.5, lines 25-26 where 6 Kpa equals 2 inches of mercury) in order to remove residual nitrogen present from the end of previous sterilization cycle (col.5, lines 21-23), adding steam (col.5, lines 25-26) and heated inert gas (col.5, lines 38-39) into the sterilization chamber (figure 1:10) in order to humidify the products to be sterilized (col.5, lines 26-27) to increase chamber pressure by at least 2 inches of mercury (col.5, lines 39-40), re-evacuating by pulling the inert gas from the chamber by 2 inches of mercury (col.5, lines 25-26) in order to remove residual ethylene oxide (col.6, lines 12-13), injecting the sterilant into the chamber (figure 1:10) to raise the chamber pressure by at least 9 inches of mercury (col.5, lines 40-42), introducing an overpressure of inert gas into the single chamber in the range of from 5 to 15 inches of mercury (col.5, lines 38-40), degassing the products to a pressure of less than 3 inches of mercury (col.6, lines 22-23) in order to eliminate residual ethylene oxide and moisture from the sterilized products (col.6, lines 12-13), re-pressurizing with inert gas to a pressure of from less than 3 up to 55 inches of mercury (col.6, lines 21-22), because ethylene oxide is toxic and it needs to be substantially removed from the sterilized

products (col.6, lines 15-16), and the inert gas facilitates the steam and sterilant gas entering into cervices of the product (Popescu adds steam and dry nitrogen (col.5, lines 37-40) first then adds ethylene oxide (col.5, lines 40-41), then re-pressurizes the chamber with heated inert gas (col.5, lines 53-54) while residual steam and ethylene oxide is still present in the items (since Popescu discloses a subsequent drying phase to eliminate residual ethylene oxide and moisture as explained in col.6, lines 12-14), because the use of pure nitrogen rather than air to re-pressurize the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen (col.5, lines 55-58). As to the limitation that the steam and the sterilant gas combine without condensing, Popescu sterilizes moisture sensitive items (col.3, lines 10-30) with high concentration values of ethylene oxide (col.3, lines 65-67) rather than steam and further teaches adding steam only to moisten the products without teaching the occurring of any condensation on the products in the sterilization chamber. As such one of ordinary skill in the art trying to sterilize moisture sensitive items would readily recognize upon reading Popescu to use extremely high concentrations of ethylene oxide of up to 100% while minimally moistening the products by preventing the condensation of steam on their surfaces, because such products are made from polymers that they begin to deteriorate when they are exposed to moisture (col.3, lines 21-23).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in Joslyn with the nitrogen gas because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of

inadvertently forming an explosive mixture of ethylene oxide and oxygen as shown by Popescu (col.5, lines 55-58) and to further provide the method in Joslyn with the vacuum pressure values in order to remove residual nitrogen present from the end of previous sterilization cycles as described by Popescu (col.5, lines 21-23).

Popescu fails to teach adding pulsing steam. Irons discloses a method of sterilization using pulsing steam (col.1, lines 15-16), because such a process insures that all fabric and porous materials will be sterilized in the shortest possible cycle for a wide range of loads (col.4, lines 35-37). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Joslyn/Popescu with a steam-pulsing step, because such a process insures that all fabric and porous materials will be sterilized in the shortest possible cycle for a wide range of loads as explained by Irons (col.4, lines 35-37).

Regarding claim 14, Joslyn discloses a method for sterilizing industrial products (col.1, lines 12-14) including, in combination, the steps of conditioning industrial products to be sterilized by placing the products in a single chamber (figure 1:16), evacuating the single chamber (col.3, lines 37-39) to a certain vacuum pressure, adding heated air into the single chamber (col.3, lines 57-58) to raise the temperature of the products (one of ordinary skill in the art would recognize that adding heated air will increase the temperature within the sterilizing chamber,16, of Joslyn), sterilizing the industrial products by injecting ethylene oxide gas into the chamber (col.4, lines 31-32) to raise the chamber pressure by a certain amount of pressure (figure 1:111 and col.4, lines 33-34) with ethylene oxide gas concentration of 650 mg/1 of sterilants gas (see

Table 2), which acts as an overpressure gas into the single chamber (col.4, lines 36-38) having a certain pressure value, holding the product in the single chamber for a dwell time (see the two hours ethylene oxide sterilization described in Table 2) while the product is sterilized, evacuating the chamber to a certain pressure value (considered P1 in figure 3 and as described in col.5, lines 15-18), adding steam into the single chamber (col.5, lines 15-19), adding steam into the single chamber (col.3, lines 44-45) and injecting the single chamber with warm air (col.5, lines 29-30), degassing the products by a gas wash that includes steam (col.5, lines 9-10) and evacuating the chamber to a certain pressure value (considered P1 in figure 3 and as described in col.5, lines 15-18) and re-pressurizing with heated air to a certain pressure value (col.5, lines 29-32) with necessary repetitions of evacuating and re-pressuring the chamber to degas the products (col.6, lines 25-32) without specified holding times (col.6, lines 27-32), releasing the degassed products after the steps of conditioning the products, sterilizing the products, and de-gassing the products are completed (col.6, lines 32-34) to specific product parameters (col.6, lines 37-45 and Table 2). Joslyn fails to teach the following: introducing 5 to 15 inches of nitrogen overpressure into the chamber, evacuating the single chamber to a pressure of from 1 to 3 inches of mercury, pulsing steam, and degassing with an inert gas.

Popescu discloses a method for sterilizing industrial products with ethylene oxide gas (col.1, lines 6-11) that includes the following: evacuating the sterilizing chamber (figure 1:10) to a pressure of from 1.77 inches of mercury (col.5, lines 25-26 where 6 Kpa equals 2 inches of mercury) in order to remove residual nitrogen present from the

end of previous sterilization cycle (col.5, lines 21-23), introducing an overpressure of nitrogen gas into the single chamber in the range of from 5 to 15 inches of mercury (col.5, lines 38-40), because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen (col.5, lines 55-58), and degassing the products with an inert gas (col.6, lines 21-22), because ethylene oxide is toxic and it needs to be substantially removed from the sterilized products (col.6, lines 15-16).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in Joslyn with the nitrogen gas because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen as shown by Popescu (col.5, lines 55-58) and to further provide the method in Joslyn with the vacuum pressure values in order to remove residual nitrogen present from the end of previous sterilization cycles as described by Popescu (col.5, lines 21-23). Popescu fails to teach pulsing steam. Irons discloses a method of sterilization using pulsing steam (col.1, lines 15-16), because such a process insures that all fabric and porous materials will be sterilized in the shortest possible cycle for a wide range of loads (col.4, lines 35-37). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Joslyn/Popescu with a steam-pulsing step, because such a process insures that all fabric and porous materials will be sterilized in the shortest possible cycle for a wide range of loads as explained by Irons (col.4, lines 35-37).

Regarding claim 3, Joslyn sterilizes industrial products with ethylene oxide in a single chamber (figure 1:16) by evacuating the single chamber (col.4, lines 1-3 and figure 2:106 and 107) after holding the products in the single chamber and adding steam (col.3, lines 44-47) into the single chamber.

Regarding claim 4, Joslyn fails to teach the use of heated nitrogen gas. Popescu discloses a method for sterilizing industrial products with ethylene oxide gas (col.1, lines 6-11) that includes adding heated nitrogen gas (col.5, lines 38-39) into the sterilization chamber (figure 1:10) because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen (col.5, lines 55-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method in Joslyn with the heated nitrogen gas because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen as shown by Popescu (col.5, lines 55-58).

Regarding claims 6, 13, and 15, Joslyn discloses degassing the products by evacuating the single chamber (col.5, lines 15-16) and then pressurizing it with heated air (col.5, lines 29-30) and repeating until the products are degassed (col.6, lines 25-32). Joslyn fails to disclose pressure values for vacuum or for pressurizing and also fails to teach the use of nitrogen. Popescu discloses a method for sterilizing industrial products with ethylene oxide gas (col.1, lines 6-11) that includes the following: evacuating to a pressure of from 1.77 inches of mercury (col.5, lines 25-26 where 6 Kpa

equals 2 inches of mercury) in order to remove residual nitrogen present from the end of previous sterilization cycle (col.5, lines 21-23), introducing an overpressure of inert gas into the single chamber in the range of from 5 to 15 inches of mercury (col.5, lines 38-40), because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen (col.5, lines 55-58), and the rate of degassing is in the range of 0.1 to 0.5 inches per minute (col.6, lines 27-28, 0.83 Kpa/min is equivalent to 0.24 inches of mercury/min).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in Joslyn with the nitrogen gas, because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen as shown by Popescu (col.5, lines 55-58), and to further provide the method in Joslyn with the vacuum pressure values in order to remove residual nitrogen present from the end of previous sterilization cycles as described by Popescu (col.5, lines 21-23).

Regarding claim 16, Joslyn uses ethylene oxide to sterilize industrial products by adding steam into the single chamber (figure 1:16) and is repeated one or more times (col.6, lines 21-32).

8. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joslyn (U.S.P.N. 4,770,851) in view of Popescu et al (U.S.P.N. 5,464,580), and Irons et al (U.S.P.N. 3,494,725) as applied to claim 4 and further in view of Stewart et al (U.S.P.N. 5,882,590).

Regarding claim 5, Joslyn and Irons fail to teach vacuum pressure values and they also fail to teach placing real-time ethylene oxide monitors in the headspace of the chamber. Popescu discloses a method for sterilizing industrial products with ethylene oxide gas (col.1, lines 6-11) that includes evacuating to a pressure of from 1.77 inches of mercury (col.5, lines 25-26 where 6 Kpa equals 2 inches of mercury) in order to remove residual nitrogen present from the end of previous sterilization cycle (col.5, lines 21-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in Joslyn with the vacuum pressure values in order to remove residual nitrogen present from the end of previous sterilization cycles as described by Popescu (col.5, lines 21-23).

Popescu fails to teach placing real-time ethylene oxide monitors in the headspace of the chamber. Stewart uses real-time monitoring method (col.1, lines 6-8) where various parametric sterilization variables (col.3, lines 38-43) are sensed including a real-time ethylene oxide concentration sensor (col.3, lines 43 and 63) by placing this sensor in the headspace of the sterilization chamber (figure 1:1 and 8) in order to assure that critical concentration parameter values have been met (col.2, lines 61-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Joslyn/Popescu/Irons with the concentration real-time sensor being placed in the headspace of the chamber in order to assure that critical concentration parameter values have been met as shown by Stewart (col.2, lines 61-65).

Regarding claim 10, Joslyn and Irons fail to teach pressurizing values and also fails to teach the use of nitrogen gas. Popescu discloses pressurizing the sterilization chamber (figure 1:10) with 3 to 50 inches of mercury with nitrogen (col.6, lines 21-22), because ethylene oxide is toxic and it needs to be substantially removed from the sterilized products (col.6, lines 15-16). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Joslyn/Irons with the nitrogen gas, because ethylene oxide is toxic and it needs to be substantially removed from the sterilized products as explained by Popescu (col.6, lines 15-16).

9. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joslyn (U.S.P.N. 4,770,851) in view of Popescu et al (U.S.P.N. 5,464,580),Irons et al (U.S.P.N. 3,494,725), and Stewart et al (U.S.P.N. 5,882,590) as applied to claim 5 and 10, and further in view of Kolstad et al (U.S.P.N. 4,973,449).

Regarding claim 11, Joslyn, Popescu, Irons, and Stewart fail to teach evacuating the single chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas. Kolstad teaches pulsing by evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas (col.5, lines 30-36) in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors for more efficient sterilization of the contents (col.5, lines 30-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Joslyn/Popescu/Irons/Stewart with the pulsing process of Kolstad in order to subject the contents of the sterilization chamber to

pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors for more efficient sterilization of the contents as described by Kolstad (col.5, lines 30-41).

Regarding claim 12, Joslyn degassing step is further accomplished by injecting the single chamber (figure 1:16) with warm air (col.5, lines 29-30).

10. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joslyn (U.S.P.N. 4,770,851) in view of Popescu et al (U.S.P.N. 5,464,580) and Irons et al (U.S.P.N. 3,494,725) as applied to claims 3 and 6, and further in view of Kolstad et al (U.S.P.N. 4,973,449).

Regarding claim 7, Joslyn, Popescu, and Irons fail to teach evacuating the single chamber down to 3 to 7 inches of mercury and also fail to teach pulsing the single chamber with 5 to 9 inches of heated nitrogen gas. Kolstad teaches pulsing by evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas (col.5, lines 30-36) in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors for more efficient sterilization of the contents (col.5, lines 30-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Joslyn/Popescu/Irons with the pulsing process in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors for more efficient sterilization of the contents as described by Kolstad (col.5, lines 30-41).

Regarding claim 8, Joslyn describes that the step of degassing is further accomplished by injecting the single chamber with warm air (col.5, lines 29-30).

Response to Arguments

11. Applicant's arguments filed on 3/13/08 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches a range of 150-550 mg/L for the sterilant gas. Examiner disagrees. Applicant points to the specification at page 5 where it discloses a drop from 450-150 mg/L. This appears to be a monitor of chamber evacuation, not a range of concentration useful in sterilizing. Examiner believes that 150 mg/L is representative of a residual concentration of ethylene oxide gas -- not a sterilizing concentration.

On pages 10-11 of the Remarks section; Applicant argues that Joslyn's method of sterilization requires the air and steam to condense on the interstices of the load, that neither Joslyn's method nor Propescu's provides or disclose a dynamic mechanism of adding steam then injecting heated inert gas, that the cited references do not teach injecting the sterilant first and then overlays the inert gas to provide a dynamic mechanism of shifting the highest sterilant gas concentration from the load surface to its center, and that the cited reference do not teach pulsing in heated nitrogen which in combination with other steps in claim 14 provides a dynamic mechanism of delivering/pushing the heat of the steam into the load by the nitrogen gas through a pressure gradient between the chamber headspace and the load center.

Popescu sterilizes moisture sensitive items (col.3, lines 10-30) with high concentration values of ethylene oxide (col.3, lines 65-67) rather than steam and further teaches adding steam only to moisten the products without teaching the occurring of any condensation on the products in the sterilization chamber. As such one of ordinary skill in the art trying to sterilize moisture sensitive items would readily recognize upon reading Popescu to use extremely high concentrations of ethylene oxide of up to 100% while minimally moistening the products by preventing the condensation of steam on their surfaces, because such products are made from polymers that they begin to deteriorate when they are exposed to moisture (col.3, lines 21-23). In addition, the combination of Joslyn (injecting steam)/Popescu (injecting heated inert gas) result in having the dynamic mechanism in order to humidify the products to be sterilized (col.5, lines 26-27) by increasing the chamber pressure by at least 2 inches of mercury (col.5, lines 39-40).

As to the argument that the cited references do not teach injecting the sterilant first and then overlays the inert gas to provide a dynamic mechanism of shifting the highest sterilant gas concentration from the load surface to its center, the combination of Joslyn and Popescu meet this feature. Joslyn injects ethylene oxide first so that both steam and ethylene oxide penetrates deep within the items (col.4, lines 36-41) and Popescu introduces an overpressure of nitrogen gas into the single chamber in the range of from 5 to 15 inches of mercury (col.5, lines 38-40), because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen (col.5, lines

55-58). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in Joslyn with the nitrogen gas because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen as shown by Popescu (col.5, lines 55-58).

As to the argument that the cited reference do not teach pulsing in heated nitrogen which in combination with other steps in claim 14 provides a dynamic mechanism of delivering/pushing the heat of the steam into the load by the nitrogen gas through a pressure gradient between the chamber headspace and the load center, instant claim 14 cites the limitation of pulsing the heated inert gas in the alternative form. Furthermore, claim 14 does not recite the feature of describing the chamber headspace.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. R. C./

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797